K 100035

MAR 17 2010

510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92(a).

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE PREPARED

a. Applicant:
Carl Zeiss Meditec AG
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Germany

b. Contact Person:
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c. Date Prepared: November 20, 2009

NAME OF DEVICE, INCLUDING TRADE NAME & CLASSIFICATION NAME

a. Trade/Proprietary Name: VISULAS 532s Laser System with the *VITE* option
b. Common/Usual Name: Ophthalmic surgical laser
c. Classification Name: Laser Instrument, Surgical, Powered
d. Classification Code: 21 CFR §878.4810; 79 GEX

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PREDICATE DEVICES

PREDICATE DEVICE	MANUFACTURER	510(K) CLEARANCE NUMBER	CLEARANCE DATE
VISULAS 532s	Carl Zeiss Meditec AG	K013402	November 14, 2001
PASCAL Photocoagulator	OptiMedica Corporation	K043486	March 3, 2005
PASCAL Synthesis Delivery System	OptiMedica Corporation	K081744	September 9, 2008
PASCAL Photocoagulator	OptiMedica Corporation	K091966	July 15, 2009
PASCAL Streamline Photocoagulator	OptiMedica Corporation	K092621	September 25, 2009

DEVICE DESCRIPTION

The VISULAS 532s Laser System with the *VITE* option is an ophthalmic surgical laser intended for use in photocoagulating ocular tissues in treatment of diseases of the eye. As with the predicate device, laser energy for the proposed device is delivered via transpupillary delivery or intraocular endoprobe delivery. The VISULAS 532s Laser System with the *VITE* option includes an optional new laser slit lamp (the LSL 532s *VITE*) that features a multi-spot treatment cascade delivery option.

STATEMENT OF INTENDED USE

The VISULAS 532s Laser System with the *VITE* option is intended for use in retinal, panretinal, focal and grid photocoagulation of ocular tissues in the treatment of diseases of the eye including:

- Proliferative and non-proliferative diabetic retinopathy
- Macular edema
- Branch and central retinal vein occlusion
- Lattice degeneration
- Retinal tears and detachments

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The VISULAS 532s Laser System with the *VITE* option has the same operating characteristics and is substantially equivalent to the predicate VISULAS 532s Laser System, also by Carl Zeiss Meditec (K013402). Both the predicate and proposed devices deliver laser energy via the Laser Slit Lamp (LSL), the Laser Indirect Ophthalmoscope LIO 532 (for transpupillary delivery) or the endoprobe (for intraocular delivery). The primary

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modification incorporated in the VISULAS 532s Laser System is the addition of an alternative laser slit lamp that is equipped with the *VITE* functionality, which allows the option of delivering a multi-spot treatment.

BRIEF SUMMARY OF NONCLINICAL TESTS & RESULTS

The VISULAS 532s Laser System with the *VITE* option has been designed and tested to applicable safety standards. The determination of substantial equivalence is based on the comparison between the results of performance data conducted using the VISULAS 532s with the *VITE* option and the predicate device. These results demonstrate the ability of the proposed device to produce photocoagulation of ocular tissues that is comparable to the photocoagulation produced by the predicate device.

CONCLUSION

The VISULAS 532s Laser System with the *VITE* option is substantially equivalent to the predicate device, the VISULAS 532s Laser System (K013402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 17 2010

Carl Zeiss Meditec, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K100035
Trade/Device Name: VISULAS 532s Laser System with the *VITE* option
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulatory Class: Class II
Product Code: GEX
Dated: March 08, 2010
Received: March 09, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

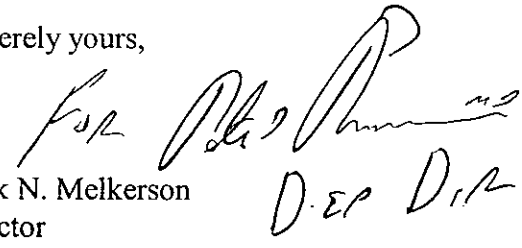
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K100635

Device Name(s): VISULAS 532s Laser System with the *VITE* option

Indications for Use:

The VISULAS 532s Laser System with the *VITE* option is intended for use in retinal, panretinal, focal and grid photocoagulation of ocular tissues in the treatment of diseases of the eye including:

- Proliferative and nonproliferative diabetic retinopathy
- Macular edema
- Branch and central retinal vein occlusion
- Lattice degeneration
- Retinal tears and detachments

Prescription Use X AND/OR (Part 21 CFR §801 Subpart D)

Over-The-Counter Use _____ (21 CFR§ 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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